IN THE FOOD AND DRUG ADMINISTRATION
Center for Food Safety and Nutrition
Office of Nutritional Products, Labeling, and Dietary Supplements

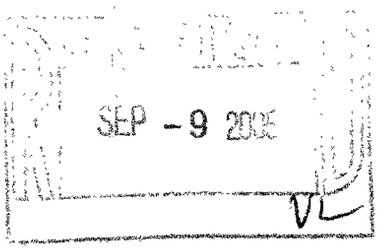
IN THE NOTIFICATION OF:

Notifier: Vigconic (International) Ltd.

Filing Date: unknown

New Dietary Ingredient(s): RADIX GINSENG, CORNU CERVI PANTOTRICHUM, FRUCTUS CNIDII, SEMEN CUSCUTAE, and KAEMPFERIAE RHIZOMA

Notifier Docket No. Vigconic=1



Date: 29 August 2005

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Dr. Susan Walker
Division Director
Division of Dietary Supplement
Office of Nutritional Products, Labeling, and Dietary Supplements
Center for Food Safety and Nutrition
Food and Drug Administration
5100 Paint Branch Parkway
College Park, Maryland 20740-3835

COMPLETE ADDRESS OF NOTIFIER AND EXPLANATORY LETTER

ATTN: Victoria Lutwak:

In accordance with our conversation of 26 August 2005, please find enclosed the complete address of the Notifier (in accordance with §190.6(b)(1)). Additionally, at the oral request of the FDA, we have included an Explanatory Letter to a reference submitted with the original submission. An original and two copies of this letter are attached herewith.

I. Address of Notifier

The notifier provides his address as:

Vigconic (International) Ltd.
5B, Cheong Wah Factory Building
39-41, Sheung Heung Road, Tokwawan
Kowloon, HONG KONG

II. Explanatory Letter

The FDA has asked for explanation to one reference for the NDI Cornu Cervi Pantotrichum (aka Pilose Antler) that was relied upon by the Notifier in concluding a dietary supplement containing the NDI will reasonably be expected to be safe. Specifically, the FDA's explanation request centered on whether the Chinese characters following the English-language terminology presented in the reference was a translation of the English-language terminology. The reference is entitled "Young Pilose Antler-A Precious Crude Drug".

We assert that the Chinese characters following the English-language terminology is a translation. For example, at page 44 of the reference, 2nd column, 2nd paragraph, the term "horn glue" is followed by Chinese characters (transliterated: "lujiao jiao"). The Chinese characters are the translation of the English-language term.

Please note that whereas the document was relied upon in concluding a dietary supplement containing the NDI will reasonably be expected to be safe, we do not intend the NDI to be used in the treatment, cure, or mitigation of a disease or condition.

Passage of the notifications to publication is respectfully requested and in order.

Respectfully submitted,

Robert DeWitty
Attorney for the Notifier
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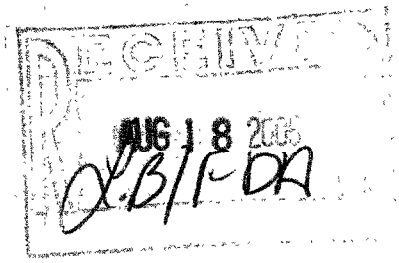
Enclosures.



11 August 2005

Susan Walker, M.D.
Division Director
Division of Dietary Supplement
Office of Nutritional Products, Labeling, and Dietary Supplements
Center for Food Safety and Nutrition
Food and Drug Administration
5100 Paint Branch Parkway
College Park, Maryland 20740-3835

Re: Premarket Notifications filing
Our Ref.: Vigconic=1

Dear Madam:

Please find attached documents relied upon by our client in concluding the new dietary ingredients, RADIX GINSENG, CORNU CERVI PANTOTRICHUM, FRUCTUS CNIDII, SEMEN CUSCUTAE, and KAEMPFERIAE RHIZOMA, contained in the dietary supplement known under the trademark VI-28, to be safe. This notification is filed on behalf of the dietary supplement manufacturer Vigconic (International) Ltd.

AIMS
2005-5241

Please note that as no statutory provision nor regulation has put forth whether notifications for multiple new dietary ingredients contained in one supplement should be submitted individually or in totale, the notifier has chosen to submit such notifications simultaneously.

Qualification as New Dietary Ingredient

The notifier hereby asserts that CORNU CERVI PANTOTRICHUM, FRUCTUS CNIDII, SEMEN CUSCUTAE and KAEMPFERIAE RHIZOMA have not been marketed in the United States (U.S.) before October 15, 1994 (10/15/94). The notifier believes RADIX GINSENG to be marketed in the U.S. before 10/15/94, but does not have conclusive proof of such.

Section 8 of the Dietary Supplement and Health Education Act of 1994 (DSHEA) states that a new dietary ingredient shall mean:

> "...a dietary ingredient that was not marketed in the United States before October 15, 1994..."[1]

In the instant cases, as CORNU CERVI PANTOTRICHUM, FRUCTUS CNIDII, SEMEN CUSCUTAE and KAEMPFERIAE RHIZOMA have not been marketed in the U.S. before 10/15/94, they qualify as new dietary ingredients (NDIs) under DSHEA. Whereas RADIX GINSENG may have been marketed before 10/15/94, the notifier does not have proof of such, and therefore classifies RADIX GINSENG as a NDI under DSHEA.

[1] Dietary Supplement and Health Education Act, 108 Stat. L. 4331 at §8 (1994).

Notifications

Notifications are required for NDIs under DSHEA.

The Dietary Supplement and Health Education Act of 1994 (DSHEA) defines a dietary ingredient to be, among other substances,

> "...(C) an herb or other botanical...(E) a dietary substance for use by man to supplement the diet by increasing the total dietary intake..."[2]

Applying the definition to the instant NDIs, FRUCTUS CNIDII, RADIX GINSENG, KAEMPFERIAE RHIZOMA, and SEMEN CUSCUTAE are ingredients because they are "...other botanical[s]...". CORNU CERVI PANTOTRICHUM qualifies as an ingredient because it is "...use[d] by man to supplement the diet by increasing the total dietary intake".

Information Submitted for NDIs

As FRUCTUS CNIDII, RADIX GINSENG, KAEMPFERIAE RHIZOMA, and SEMEN CUSCUTAE qualify as "other botanicals" under DSHEA, information sufficient for their identification has included in their respective notifications.

Under FDA regulations, notifications shall include the name of the NDI

> "...including the Latin binomial name (including the author) of any...other botanical".[3]

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[2] Id. at §3.
[3] 21 CFR 190.6(b)(2).

Therefore, the Latin binomial and author have been included for FRUCTUS CNIDII, RADIX GINSENG, KAEMPFERIAE RHIZOMA, and SEMEN CUSCUTAE.

As CORNU CERVI PANTOTRICHUM is used to increase the total dietary intake and is not classified as a botanical, the Latin binomial and author are not required to be included.

Overcoming Initial State of Adulteration

The dietary supplement VI-28 ("Supplement) contains in its formulation the NDIs. Under DSHEA, dietary supplement containing NDIs "...shall be deemed adulterated..."[4]. HOWEVER, the statute allows a manufacturer to overcome the initial state of adulteration by

> "...provid[ing] the Secretary with information...which is the basis upon which the manufacturer or distributor has concluded...a dietary supplement containing the ingredient will reasonably be expected to be safe"[5].

As the Supplement contains the previously mentioned NDIs, it is deemed adulterated under the statute. However, attached herewith is provided information upon which the manufacturer, Vigconic (International) Ltd., has concluded the Supplement to reasonably be expected to be safe.

[4] Id. note 1.
[5] Id.

Correspondingly, it is the notifier's contention that the initial state of adulteration has been overcome through this submission.

Quality and Quantity of the Submitted Information

The provided information was chosen by Vigconic (International) Ltd. and provided to the Secretary to show the basis of the manufacturer's conclusion.

Regarding the quantity and quality of the submitted information, the FDA has neither proposed nor promulgated any regulation setting standards for the type of information to be provided. In response to a comment made to the FDA's promulgated regulation for New Dietary Ingredient Notifications, the FDA stated:

> "...the statute does not specify or limit what evidence a manufacturer...may rely on in determining whether the use of the ingredient will reasonably be expected to be safe".[6]

The FDA continued:

> "The agency...in deciding what information needs to be provided, is bound by the standard of the act. It is not free to rewrite the law."[7]

Thus, the provided information was relied upon by the manufacturer when concluding the Supplement will reasonably be expected to be safe.

[6] 62 Fed. Reg. at 49888.
[7] Id.

Adulteration under DSHEA

The manufacturer has provided information to the Secretary showing how he arrived at his conclusion the Supplement will reasonably be expected to be safe under the suggested conditions of use.

Under DSHEA, a dietary supplement that contains a dietary ingredient shall be deemed adulterated if:

> "..[it] is a new dietary ingredient for which there is inadequate information to provide reasonably assurance that such ingredient does not present a significant or unreasonable risk of illness or injury"[8]

The statute continues:

> "...the United States shall bear the burden of proof on each element to show that a dietary supplement is adulterated".[9]

In the instant case, the manufacturer has overcome the initial state of adulteration through providing information to the Secretary showing the basis for his conclusion of reasonably expectation of safety. If the FDA asserts that the Supplement is adulterated under DSHEA, it must be required to meet the burden of why the notifiers provided information is inadequate **to provide a reasonable assurance that the ingredients do not present a significant or unreasonable risk of illness or injury.** Merely stating the information to be inadequate does not meet the burden of proof as required by DSHEA.

[8] Id. note 1 at §4.
[9] Id.

In the Senate bill 784, which was enacted as DSHEA, a dietary supplement was not be deemed adulterated unless it "may be" injurious or "ordinarily" injurious to be population under the conditions of use recommended in the labeling[10].

In the instant case, the Supplement's conditions of use are as follows:

Conditions of Use

First Month	1 time daily, 2 capsules each time;
Second and Third Month	1 time every 2 days, 2 capsules each time;
Fourth Month and as desired	2 times every week, 2 capsules each time.

The amount of the NDIs contained within each serving size are as follows:

Amount per serving size:

Radix Ginseng
Cornu Cervi Pantotrichum
Fructus Cnidii
Semen Cuscutae
Kaempferiae Rhizoma

A determination of adulteration by the FDA based on inadequate information must be addressed to the conditions of use as indicated by the manufacturer. A failure to supply information directed to the conditions of use will make such determination arbitrary and capricious.

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[10] *see* S. Rept. 103-410 at pg. 36.

Acknowledgement of receipt of the attached notifications and their publication is respectfully requested and in order.

Respectfully Provided,

Robert M. DeWitty
Attorney for the Notifier
tele: 410-539-6969
fax: 410-510-1973

New Dietary Ingredient Notification

Common Name: Radix Ginseng

Latin Binomial: Panax ginseng

Author: (C.A. Mey.) Carl Anton von Meyer

Direction for Use: see cover sheet pg. 7

Provided Information

1. Information on FeminiCare™ formula containing the ingredient (visited November 11, 2003) <http://www.dreampharm.com/Item/216.htm>.

2. Ingredient listing for Viatexx™ containing the ingredient (visited November 11, 2003) <http://www.strenixx.com/products/viatexx_for.htm>.

3. Ingredient listing for BetterMAN™ herbal supplement showing the ingredient (visited October 23, 2003) <http://www.bettermannow.com/faq/html>.

4. Study performed on BetterMAN™ herbal supplement showing no side effects or adverse reactions following administration of the supplement (visited October 23, 2003) <http://www.bettermannow.com/researchstudies.html>.

5. Extract from the German Commission E. monograph, showing dosage of Radix Ginseng in an amount of a daily dose of 1-2 g.
Witchl, M. "Herbal Drugs and Phytopharmaceuticals: A handbook for practice...," pp. 236-238,